

Application Serial No.: 09/636,387
Filing Date: August 9, 2000

REMARKS

Prior to this amendment, claims 49-54 and 61-75 were pending in this application. Claims 49 and 61 have been amended. Support for the amendments can be found throughout the specification. See e.g., page 7, lines 7-24; page 21, lines 30-33; page 28, lines 19-30. Claims 50-52 have been amended to correct antecedent basis. Claims 63, 64, 66, 68, and 72 have been amended to add further claim dependency. Claim 76 is new. Support for the new claim can be found in the specification, e.g., page 9, lines 1-2. No new matter has been added by way of these amendments. Applicants respectfully request entry of the amendments.

Interview

Applicants appreciate the Examiner's interview of March 3, 2004. In the interview, Applicants' representative and the Examiner discussed the rejections in the office action. Specifically, Applicants' representative and the Examiner discussed the rejections of the claims under 35 U.S.C. § 103 over Walt in view of Brenner. There was a discussion about the teachings of the Walt reference and discussion of characteristics of the present invention that potentially differ from that in Walt. However, Applicants' representative and the Examiner did not reach agreement regarding any of the rejections. Nonetheless, the Examiner's position regarding certain rejections is more clear. It is hoped that the comments and amendments submitted herein overcome these rejections.

Rejection under 35 U.S.C. § 132

The Examiner objects to Applicants' amendment to the specification as adding new matter under 35 U.S.C. § 132. While Applicants disagree with this position, Applicants submit that the rejection is moot as the difference in priority claimed by Applicants and that proposed by the Examiner has no effect on any other rejections, i.e., none of the cited references have an effective filing date between the priority date claimed and that proposed by the Examiner.

Rejection under 35 U.S.C. § 103(a)

Claims 49-54, 61-63, 65-69 and 71-74 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Walt, *et al.* (U.S. Patent No. 6,327,410 B1) in view of Brenner, *et al.* (U.S. Patent No. 5,863,722) and in view of the definition of Morris, ed. (Academic Press Dictionary of Science and Technology, Academic Press, 1992, page 821).

The Examiner's position appears to be that Walt teaches all elements of the rejected claims except that "they do not specifically teach at least one microsphere subpopulation does not have an optical signature." Moreover, the Examiner asserts that Brenner provides this element and that one of

1133870_1

5

Application Serial No.: 09/636,387

Filing Date: August 9, 2000

ordinary skill in the art would have been motivated to apply the microspheres not having an optical signature as taught by Brenner and the non-optical encoding taught by Walt to the microsphere compositions of Walt and to provide at least one subpopulation of microsphere without an optical signature thereby eliminating the need to provide optical signatures on all the microspheres for the benefit of simplicity. Applicants respectfully traverse.

In rejecting claims under 35 USC § 103(a), the Patent Office bears the initial burden of establishing a *prima facie* case of obviousness. See MPEP § 2142; see also *In re Bell*, 26 USPQ2d 1529, 1530 (Fed. Cir. 1993). To establish a *prima facie* case, three basic criteria must be met. First, the prior art must provide one of ordinary skill in the art with a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or to combine their teachings. See *WMS Gaming Inc. v. Int'l Game Tech.*, 51 USPQ2d 1385, 1397 (Fed. Cir. 1999). The mere fact that references could be modified or combined does not render the resulting modification or combination obvious unless the prior art also suggests the desirability of the modification or combination. See *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990). Second, the prior art must provide one of ordinary skill in the art with a reasonable expectation of success. The skilled artisan, in light of the teachings of the prior art, must have a reasonable expectation that the modification or combination suggested by the Examiner would be successful. See *In re Dow*, 5 USPQ2d 1529 (Fed. Cir. 1988). Third, the prior art, either alone or in combination, must teach or suggest each and every limitation of the rejected claims. The teaching or suggestion to make the claimed invention, as well as the reasonable expectation of success, must come from the prior art, and not in Applicant's disclosure. See *In re Vaack*, 20 USPQ2d 1438 (Fed. Cir. 1991). If any one of these criteria is not met, *prima facie* obviousness is not established.

Amended claim 49 is directed to a method of determining the presence of a target analyte in a sample comprising acquiring a first data image of a random array composition, storing the first data image in a computer readable memory, thereby creating a stored first data image, contacting the random array composition with the sample, acquiring a second data image from the array with the sample, storing the second data image in a computer readable memory, thereby creating a stored second data image, and comparing the first and second stored data images to determine the presence or absence of target analyte, wherein a computer processor registers the first and second stored data images by aligning the fiducial in the first and second stored data images to allow the comparison of the images.

Similarly, amended claim 61 is directed to a method of determining the presence of a target analyte in a sample comprising providing a registered first data image of a random array composition wherein the registered first data image is stored in a computer readable memory thereby creating a first stored data image, contacting the random array composition with the sample, acquiring a second data image from the array with the sample, storing the second data image in a computer readable memory,

1133870_1

Application Serial No.: 09/636,387

Filing Date: August 9, 2000

thereby creating a stored second data image, and comparing the first and second stored data images to determine the presence or absence of the target analyte, wherein a computer processor registers the first and second stored data images by aligning the fiducial in the first and second stored images to allow the comparison of the images.

Claims 49 and 61 recite storing images of the first and second data images in a computer readable memory, wherein a computer processor registers the stored first and second stored data images to allow the comparison of the images. Specifically, the claims set forth that the computer registers the images by aligning the fiducials so that the images are aligned and can be compared.

The present claims are not taught or suggested by Walt and Brenner, taken alone or in combination, because the present claims require storing images in a computer memory, registering the stored images, and alignment of the stored images. The Examiner has not pointed to any teaching in the cited references that includes steps carried out by a computer as presently claimed. Namely, the Examiner has pointed to no teaching in the cited references of a method that includes storing images of the first and second data images in a computer readable memory, wherein a computer processor registers the stored first and second stored data images by aligning a fiducial in the first and second stored data images to allow the comparison of the images. Thus, because neither Brenner nor Walt, alone or in combination, teach all the elements of the instant invention, *prima facie* obviousness has not been established.

In addition, Applicants maintain there is no motivation to combine the references to arrive at the instant invention. There is no suggestion in either reference to modify or combine the references to yield a method of determining the presence of target analyte using a computer to store, register, and align data images of random arrays. Even assuming, *arguendo*, that such a motivation existed, the skilled artisan would not have a reasonable expectation of success since the combination of references fails to teach the use of the computer as presently claimed.

In view of the fact that *prima facie* obviousness has not been established, Applicants respectfully request withdrawal of the rejection as applied to claims 41 and 61, as well as, the claims dependent therefrom.

Rejection under 35 U.S.C. § 103(a)

Claims 64, 70, and 75 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Walt, *et al.* (U.S. Patent No. 6,327,410 B1) in view of Brenner (U.S. Patent No. 5,863,722) and in view of the definition of Morris, ed. (Academic Press Dictionary of Science and Technology, Academic Press, 1992, page 821) as applied to Claims 49 and 61 above and further in view of Augenlicht (U.S. Patent No. 4,981,783).

The Examiner cites Augenlicht for the proposition that it would have been obvious to the skilled artisan to modify the substrate of Walt by utilizing a fiducial edge as taught by Augenlicht to reduce

Application Serial No.: 09/636,387

Filing Date: August 9, 2000

operator time and error by permitting automated scanning of the substrate for the expected benefit of rapid and accurate target analysis as suggested by Augenlicht. Applicants respectfully disagree.

The applicable legal standard regarding obviousness and the distinction regarding Brenner and Walt are discussed above and are incorporated at this point by reference.

The claims at issue are all dependent from amended claim 49 which is directed to a method of determining the presence of a target analyte in a sample comprising acquiring a first data image of a random array composition, storing the first data image in a computer readable memory, thereby creating a stored first data image, contacting the random array composition with the sample, acquiring a second data image from the array with the sample, storing the second data image in a computer readable memory, thereby creating a stored second data image, and comparing the first and second stored data images to determine the presence or absence of said target analyte, wherein a computer processor registers said first and second stored data images by aligning said fiducial in said first and second stored data images to allow the comparison of said images.

As noted above, Walt and Brenner, taken alone or in combination, do not teach or suggest the present claims because, in part, the present claims require storing images in a computer memory, registering the stored images, and aligning the stored images. Moreover, Applicants submit that Augenlicht fails to cure this deficiency in the other references because Augenlicht, when taken alone or in combination with the other two references, does not teach or suggest the use of the computer as presently claimed.

Augenlicht discloses the use of a scanner and imaging device to record the optical density of each clone on the film. Augenlicht, however, does not teach storing the first and second data images in a computer readable memory, wherein a computer processor registers the stored data images and aligns the fiducial in the images to allow comparison of the images. In fact, Augenlicht requires the entry of the position of the fiducials, each standard, and the intersection of the grids which are the position of the clones. *Id.* at column 8, lines 17-22. These data points are then used to orient the scanned films in order to calculate the optical densities of the clones. However, there is no teaching or suggestion in Augenlicht of storing, registering, and aligning first and second data images for comparison.

Based on the discussion in the previous section, as well as, the teachings of Augenlicht, none of the cited references or their combination teach the invention as claimed in claim 49. If none of the references teaches, alone or in combination, all the elements of the claim, then *prima facie* obviousness has not been established. Thus, Applicants respectfully request withdrawal of the rejection.

Application Serial No.: 09/636,387
Filing Date: August 9, 2000

CONCLUSION

Applicants note that the claims are ready for allowance and the Examiner is respectfully requested to provide early notification to this effect.

Please direct further questions in connection with this Application to the undersigned at (415) 781-1989.

Respectfully submitted,
DORSEY & WHITNEY LLP

Dated: April 1, 2004

Customer Number: 32940
Dorsey & Whitney LLP
Four Embarcadero Center, Suite 3400
San Francisco, CA 94111-4187
Telephone: (415) 781-1989
Facsimile: (415) 398-3249

BY: David C. Foster

David C. Foster, Reg. No. 44,685 for
Robin M. Silva, Reg. No. 38,304
Filed under 37 C.F.R. § 1.34(a)